Food and Drug Administration
Center for Drug Evaluation and Research
Anti-Infective Drugs Advisory Committee
April 29, 2010

Questions for the Committee

Based on the information presented from Study 13, please comment on the following questions regarding artesunate rectal suppository, in the context of the proposed use as a single dose for the initial treatment of patients with acute malaria who cannot take medication by mouth and for whom parenteral antimalarial treatment is not available. Treatment must be followed by effective oral or parenteral therapy for malaria as soon as possible. Artesunate rectal suppositories should not be used to prevent malaria or to treat patients who can take oral medication.

1. Discuss whether or not efficacy has been demonstrated for single dose artesunate rectal suppository. In your discussion, please address the age groups and doses of artesunate studied. If you do not believe efficacy had been demonstrated, what additional information is needed or what additional studies should be conducted?

2. Discuss whether or not safety has been demonstrated for single dose artesunate rectal suppository. In your discussion, please address the potential risks and benefits in the empirical use of the product for initial therapy of suspected malaria in patients who cannot take oral therapy nor have access to IV therapy.

3. **VOTE**: Given the overall benefits and risks, do you recommend approval of single dose artesunate rectal suppository? (Vote Yes/No)

   Please discuss your rational for your vote and comment on the following (as appropriate):

   - If your answer is yes, please discuss the artesunate rectal suppository dose(s) and age group(s). Please also discuss what studies, if any, should be performed post-approval.
   - If your answer is no, what additional studies would be needed to demonstrate that artesunate rectal suppository is safe and effective?